

A Clinical Study of the Results of Cementless Total Hip Replacement

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Summary. We introduce our total hip prosthesis, its operation technique, and report the clinical results. Ours does not use bone-cement, but its design, together with the use of original bone and new bone formation surrounding it, results in a biological anchoring.

Since 1978, we developed for this new type of total hip prosthesis 6 sizes of stem to fit more rigidly within the intramedullary canal of femur. The new femoral component also has larger notches on its surface than did the old one.

Our results of 144 cases (147 joints) ranging from 2 to 10 postoperative years giving an average of 4.4 years, are quite satisfactory.

Blood loss during the operation is as little as 480 ml. The few complications observed differ from those of the Charnley type, and will be reduced greatly when the operation is yet more cautiously and skillfully done.

Unilateral replacement in bilaterally affected patients improved the condition of the unoperated side in 30% of the cases.

Zusammenfassung. Wir stellen unsere Hüftgelenk-Totalprothese und ihre Operationstechnik vor und geben einen Bericht über die klinischen Ergebnisse. Unsere Prothese wird nicht mit Zement fixiert. Ihre Gestaltung führt jedoch, gemeinsam mit der Ausnutzung des natürlichen Knochens und einer umgebenden Knochenneubildung, zu einer direkten Fixation.

Seit 1978 haben wir für diesen neuen Prothesentyp 6 Schaftgrößen entwickelt, um sie fester in die Femurmarkhöhle einzupassen. Die neue Kopfprothese hat an ihrer Oberfläche auch größere Vertiefungen als die alte.

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Unsere Ergebnisse von 144 Fällen (147 Gelenke), die zwischen 2-10 Jahren und durchschnittlich 4,4 Jahre nach der Operation liegen, sind durchaus zufriedenstellend.

Der Blutverlust während der Operation betrug nur 480 ml. Die wenigen beobachteten Komplikationen unterscheiden sich von denen der Charnley-Prothese und werden wesentlich herabgesetzt, wenn die Operation sorgfältiger und mit mehr Erfahrung ausgeführt werden wird.

Die einseitige Operation beim doppelseitigen Hüftgelenkbefund verbesserte die Verhältnisse an der nichtoperierten Seite in 30% der Fälle.

Introduction

Adhering a total hip prosthesis using bone cement, a process reported in previous papers, leaves some problems unresolved. For example, several years after the operation, some cases show at the contact surfaces a loosening between bone and bone cement, causing subsequent pain. Others show the entire detachment of both hip prosthesis and the bone cement. For these reasons a method using no bone cement offers the best answer, providing that adequate fixation is achieved. Our total prosthesis is designed to satisfy this requirement in that new bone formation is used for direct fixation through what we term the "self-locking" method. This was developed in 1972, based on both mechanical studies and animal experiments.

Total Hip Prosthesis

Our total hip prosthesis is composed of 2 parts, an acetabular component and a femoral component. The former consists of a stainless steel socket with a 7 mm-thick plastic cup (High Density Polyethylene: HDP) screwed in to place. There are three large pagoda-

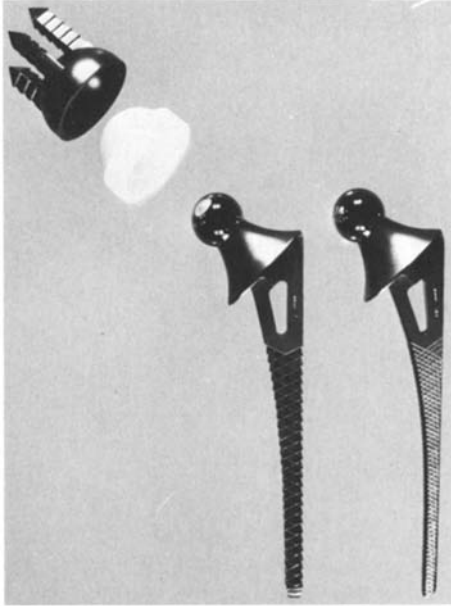


Fig. 1. Our total hip prosthesis. Right: old type femoral component used at the beginning. The stem is slender and gently curved. Left: new type femoral component used from 1978 on

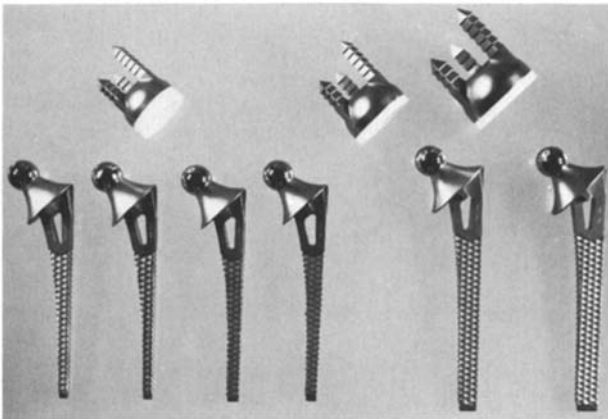


Fig. 2. Our new total hip prosthesis. Six sizes in all

shaped spikes at the base; for direct fixation these are hammered directly into the acetabulum of the pelvis.

The femoral component is also made of stainless steel, its head being 23 mm in diameter. The basal part of the stem contains a large fenester wherein chips of spongy bone are implanted upon the insertion of the component into the femur. After the operation the implanted bone chips become a bony bar implanted against the inner walls of the medullary canal. This self-locking effect fixes the femoral component to the femur. The surface of the stem of the femoral component has notches where new bone formation occurs, thus strengthening its self-locking effect. The prevent rotation of the stem within the medullary

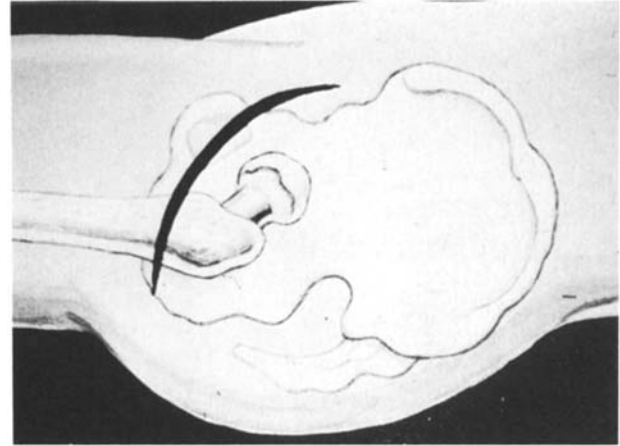


Fig. 3. Skin incision using Ollier's method

canal, the stem's transverse section is made rectangular in shape—it has a “dorsal fin” at the base. Bilateral stoppers at the center of the stem base prevent its sliding toward the lesser trochanter.

At the beginning of the present study we used the slender and gently curved stem (old type) indicated in Fig. 1. In studying long term follows-up, however, we came to the conclusion that in order to ensure the stability of the stem within the large femoral medullary canal, its size should correspond to the inner diameter of that canal. Thus (Fig. 2), we prepared 6 different stem sizes to fit the various sizes of this canal. Larger notches were also made on the surface of the stem of the femoral component to strengthen the self-locking effect. To facilitate insertion, the lateral edge was left straight (new type).

Without reaming the patient's acetabulum we can thus hammer in the acetabular component, preserving the cartilage of acetabulum itself. The spiked bottom of the acetabular component should contact the surface of the acetabulum as closely as possible. We therefore prepared three different acetabular component types.

Summarizing the above, our total hip prosthesis is of a low friction type, with an HDP articular surface of an acetabular component and a stainless steel femoral component.

Operation Techniques

We employ the Ollier method for skin incision (Fig. 3). Osteotomy of the greater trochanter is temporarily completed. Here we insert a wire-pulling forceps between the gluteus medius muscle and the greater trochanter in the anterior direction, then hook a Gigli saw with the tip of the forceps and lead it posteriorly. After the osteotomy of the greater trochanter, the joint capsule is resected as thoroughly as possible. We perform this resection of the femoral head on a line joining the greater

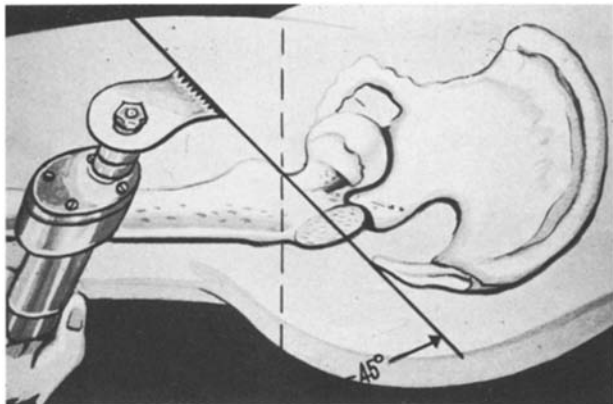


Fig. 4. We resect the femoral head on a line joining the greater and the lesser trochanter at an angle of 45° to the axis of the femur

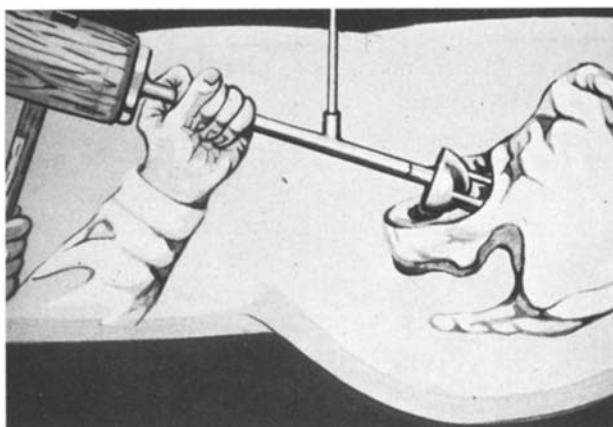


Fig. 5. The best angle of the acetabulum can be obtained by placing the major axis of the angle-finder parallel to the body axis and side arm vertical to it. The anterior opening is 10° to 15° and the horizontal opening is 30° to 40°

and the lesser trochanter at an angle of 45° to the axis of the femur (Fig. 4).

After resection of the femoral head, but before the acetabular component is hammered in, certain preparations are required. We do not ream the acetabulum, and thus we preserve the acetabular cartilage. When there are osteophytes at the medio-inferior part of the acetabulum, we resect the osteophytes as thoroughly as possible and completely insert the acetabular component.

The angle of the acetabular component insertion is optimum when the anterior opening is 10–15° and the horizontal opening 30–40°. To determine these inserting angles a special angle-finder is used. The best angle of the acetabulum can be obtained by placing the major axis of the angle-finder parallel to the body axis and the side arm vertical to it. Using the angle-finder we then open three holes in the patient's acetabulum (Fig. 5). These holes are enlarged by drill to the appropriate sizes, and the acetabular component is hammered in.

After attaching the acetabular component, the femoral component is fixed to the femur. To do this, the medullary canal is fixed to the femur. For this the canal is enlarged by a reamer which also functions as a sizer. A stem matching the

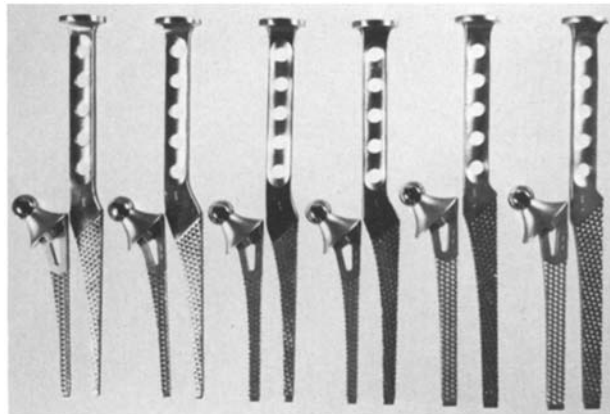


Fig. 6. There are six sizes of femoral components and raps which also function as sizers

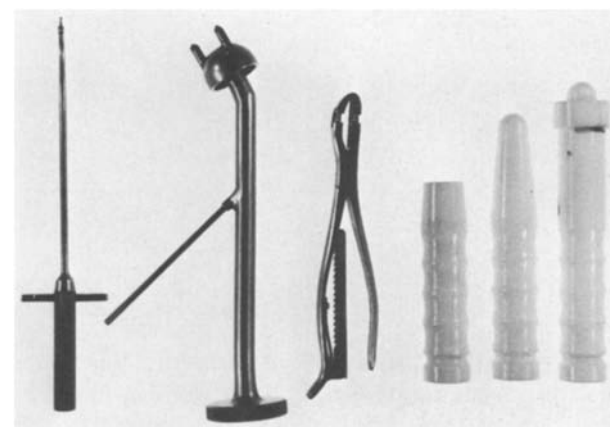


Fig. 7. Operating instruments. From left: wire-pulling forceps; angle-finder; trochanteric wire guide forceps; prosthetic drivers

size of the medullary canal is used (Fig. 6). Before inserting the stem of the femoral component, holes are drilled in the cortex of the femoral shaft in order to fasten the temporarily resected greater trochanter with stainless steel wires. Here the wires are tied in a cruciform configuration. The spongy bone is then implanted in the fenster at the basal part of the femoral component which is then inserted. The bone chips should also fill in around the component. After completing the insertion of this component, it is placed in the acetabular component. Ascertaining the smooth rotation of the total hip prosthesis, the previously resected greater trochanter is reattached in its original place. Special trochanteric wire guide forceps facilitate the cross suture of the stainless steel wire. When adductor contracture exists, normal abduction is not possible. In such a case, preoperative subcutaneous tenotomy of the adductor tendon is necessary to avoid non-union with the greater trochanter and to restore abduction of the hip.

This fixation method of total hip prosthesis is much simpler than the previously employed bone-cement method. It also has the advantages of shortening the operation time to 45 min, and reducing blood loss to an average of 480 ml. Tools used in the operation are shown in Fig. 7.

Table 1. Number of cases

Male	36 cases	39 joints
Female	161 cases	161 joints
Total	197 cases	200 joints

Age at operation (years) 20 to 81, 58.5 average

Table 2. List of cases

	No. of cases
Osteoarthritis of hip	145
Fracture of femoral neck	17
Aseptic necrosis of femoral head	19
Rheumatoid arthritis	5
Dislocation with fracture of pelvic rim	6
Ankylosis associated with tuberculosis of the hip	3
Ankylotic spondyloarthritis	2
Total	197

Postoperative Treatment

The experimental results of our basic studies indicate that bed rest and non-weight bearing are required in postoperative management until such time as the spikes on the acetabular component and the stem of the femoral component are fixed by newly formed bone. For 3 weeks following the operation the hip joint is kept abducted in an internally rotated position. Following this period, patients perform a floating exercise on the bed, flexing the hip joint. After 8 weeks patients begin an abducting exercise on the bed. After 10 weeks non-weight-bearing walking with crutches is allowed; after 12 weeks partial weight-bearing walking can be undertaken, and after 14 weeks total weight-bearing-walking with a crutch or a cane.

While the operation method using bone cement allows an earlier discharge from the hospital and our method requires a longer period of postoperative rehabilitation, this is the only drawback. The schedule of postoperative rehabilitation is based on the results of animal experimental studies which showed that the new bone formation around the total hip prosthesis is completed in 8–10 weeks. The additional time period also lessens the chance of the loosening which so often occurs in the bone-cement method. At present, after following up many cases, we believe further shortening of this postoperative rehabilitation period may be possible. Details will be mentioned later.

Table 3. Number of cases

144 Cases, 147 hip joints	
Male	25 cases (27 joints)
Female	119 cases (120 joints)

Age at operation (years)

20 to 81, 58.5 average

Postoperative follow-up (years)

2 to 9.9, 4.4 average

Cases and Their Postoperative Results

We have performed this direct fixation system of the total hip prosthesis on 197 patients (200 joints) during the 10 years from 1972 to December, 1981. This series contains all cases operated on using both old and new types of prosthesis. The details are shown in Table 1: 36 cases are males, 161 cases are females; age of the patients at the time of operation ranged from 20 to 81, with an average age of 58.5. Primary diseases are indicated in Table 2. Characteristically, secondary osteoarthritis of the hip joint is common among Japanese.

Out of 197 cases we present follow-ups of 144 over more than 2 postoperative years. Details of these 144 are shown in Table 3: 25 cases are male, 119 cases are female. The patients' ages at operation ranged from 20 to 81, the average being 58. Seventy patients were bilaterally affected; on 3 of these we performed a total bilateral hip replacement. Femoral endoprosthesis and reoperation of previously performed total hip prosthesis was also performed on 5 others.

Postoperative results were evaluated according to the standards of the Japanese Orthopaedic Association. This evaluation system consists of four factors: pain, range of motion, gait, and daily activity; each total has normal possible points: 40, 20, 20, 20 respectively. The evaluation is based on the total score of these 4 points (Table 4).

The average total preoperative score was 38.0 points. This jumped to 82.4 points after the operation, showing an average improvement of 44.4 points (Table 5). The results were thus found quite satisfactory. We compared 74 unilaterally affected cases with the 70 bilaterally affected cases. As Table 6 shows, the postoperative score of the former was 85.4 points, and the latter, 79.4 points, a difference of only 6 points.

When the unilateral replacement of the total hip prosthesis was performed on a bilaterally affected patient, the unoperated side showed improvements in 30%, no change in 58%, and aggravation in 12%.

Table 4. Hip score method: the Japanese orthopaedic association

Pain	Score	Range of motion			
		Flexion	Score	Abduction	Score
No pain	40	More than 90°	12	More than 30°	8
Pain is slight and inconstant	30	60°-89°	9	20°-29°	6
Pain is mild when walking; it disappears with rest	20	30°-59°	6	10°-19°	4
Pain is severe when walking	10	Less than 29°	3	Less than 9°	2
Pain is intense and permanent	0	Malposition of the hip or ankylosis with good position			0

Walking ability	Score	Ability to carry out daily living	Easily		
			With difficulty	Unable	diffi-culty
Normal	20	Sitting	2	1	0
		Kneeling on the floor	2	1	0
Without cane but with slight limp	15	Bowing	2	1	0
		Squatting	2	1	0
With one cane; short time without cane and with limp	10	Put on or take off stockings or socks	2	1	0
		Cut toe nail	2	1	0
Always use with canes or crutches	5	Stand up from kneeling position	2	1	0
		Stand on the affected leg only	2	1	0
None	0	Go up the stairs	2	1	0
		Go down the stairs	2	1	0

Table 5. Evaluation of results in our THR (144 cases, over 2 years after surgery)

	Before surgery	After surgery	The degree of improvement ²
Average score (points)	38.0	82.4	44.4

^a Difference of the score before and after surgery

Table 6. Evaluation of results in our THR (144 cases, over 2 years after surgery)

	No. of cases	Before surgery	After surgery	The degree of improvement ^a
Unilateral affected	74	41.7	85.4	43.7
Bilateral affected	70	34.3	79.4	45.1

^a Difference of the score before and after surgery

Table 7. Eventual histories of total score

	Before surgery	After surgery (year)				
		1	2	3	4	5
Total score (point)	38.0	83.7	84.2	84.3	84.4	84.4

We compared the postoperative scores at yearly for 5 years on 154 cases with eventual histories of more than 3 postoperative years. The results were 83.7, 84.2, 84.3, 84.4, 84.4 points respectively, indicating a continuing improved condition (Table 7).

Typical Cases

Case I (Fig. 8). Male, 45 years old, bilateral osteoarthritis of the hip joint.

Out total hip replacement (old type) was performed in May, 1972. The patient's preoperative clinical evaluation score was 38 points; now, after a postoperative period of 10 years, it is

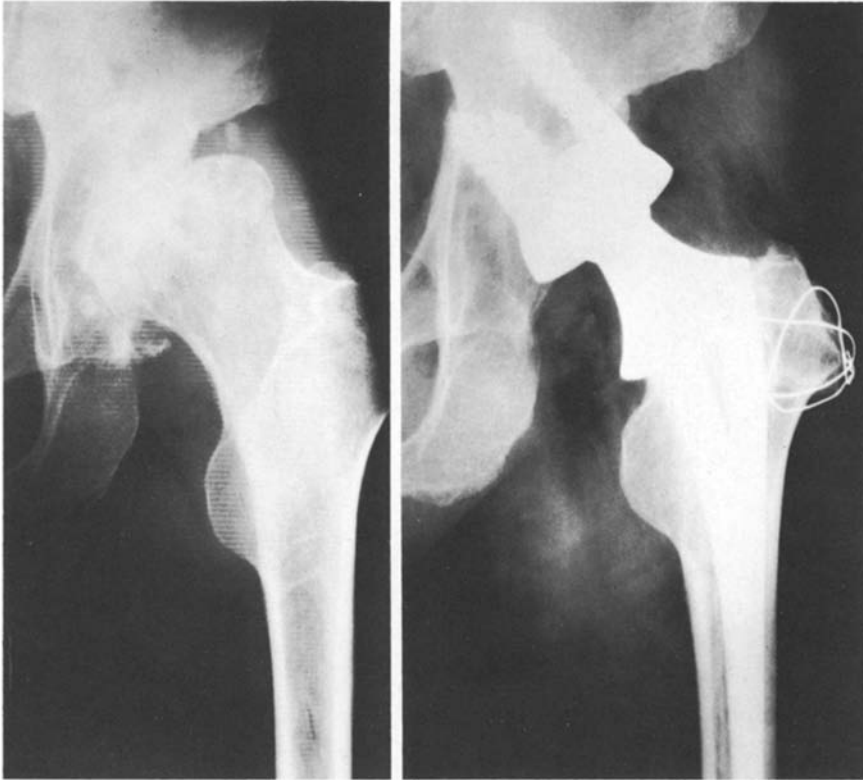


Fig. 8. Case 1: Male, 45 years old, bilateral osteoarthritis. Our old total hip prosthesis was used. His preoperative clinical evaluation score was 38 points; now, after a post-operative period of 10 years, it is a full 100 points. Left: before surgery. Right: 10 years after surgery



Fig. 9. Case 2: Female, 70 years old, left osteoarthritis. Our old total hip prosthesis was used. Her preoperative clinical evaluation score was 43 points; at present, 10 years after the operation, the score has improved to 97 points. Left: before surgery. Right: 10 years after surgery

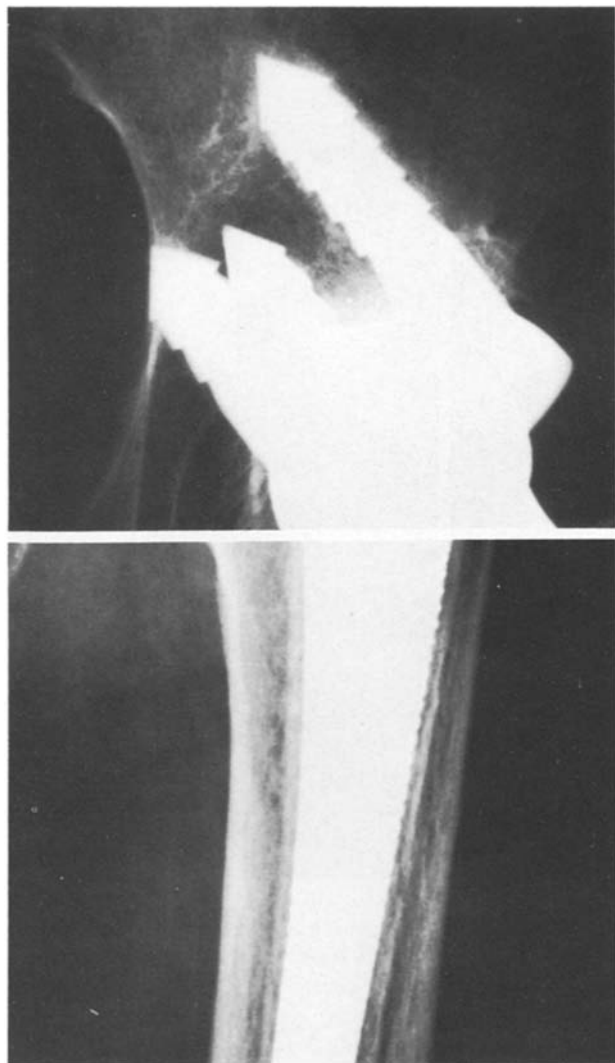


Fig. 10. Line of sclerotic margin around the stem or the socket

a full 100 points. The joint space on the opposite side opened slightly, the contour of the articular surface became clear, and clinical symptoms have improved. The results seem due to decreased weight bearing on the non-operated side caused by improved operated-side supportability.

Case 2 (Fig. 9). Female, 70 years old, left osteoarthritis of the hip joint.

Our total hip replacement (old type) was performed in January, 1972. The patient's preoperative clinical evaluation score was 43 points; at present, 10 years after the operation, the score has improved to 97 points.

X-ray Findings

Our total hip replacement using no bone cement shows radiographic characteristics different from the bone-cement method operation.

Table 8. Complications

	Number of cases
Late infection	3
Loosening	2
Non-union of great trochanter	4
Fracture of femoral shaft during surgery	2
Postoperative accident	1
Postoperative immediate dislocation	4
Total	16

1. Line of Sclerotic Margin Around the Stem or the Socket

A sclerotic margin is seen around the stem or socket within 1–3 years after the operation. Experiments have proved that these lines indicate new bone formation. Once these sclerotic margins have appeared, they do not again disappear. This differs greatly from the bone cement cases which show loosening (Fig. 10).

2. Shift of the Acetabular Component and the Stem of the Femoral Component

We have calculated the acetabular angle of our acetabular component from the angle between the line joining the lower end of right and left cotyloid notches and the line at the lateral edge of the acetabular component. The result is an angle of acetabular insertion ranging from 15° to 65°, the average being 40°. In some cases a very slow and gradual shift of the artificial socket or the stem of the femoral component has been observed. These shifting phenomenon were seen in 20.3% of the cases. The increases of the acetabular angle due to the shift of the acetabular component ranged from 3° to 25°, the average being that the 8° acetabular component ceases to shift and becomes stable after an average of 3.2 postoperative years. Shift of the tip of femoral component was observed in 9 cases: 4 with a tendency to varus, 5 with a tendency to valgus.

Complications (Table 8)

As Table 8 indicates, complications were seen in 15 cases, 7.5% of the total 197 cases (200 joints). Of these, every case of loosening (as shown in Fig. 11) seemed to be caused by the use of stems too slender for the size of the medullary canal—thus new bone formation was

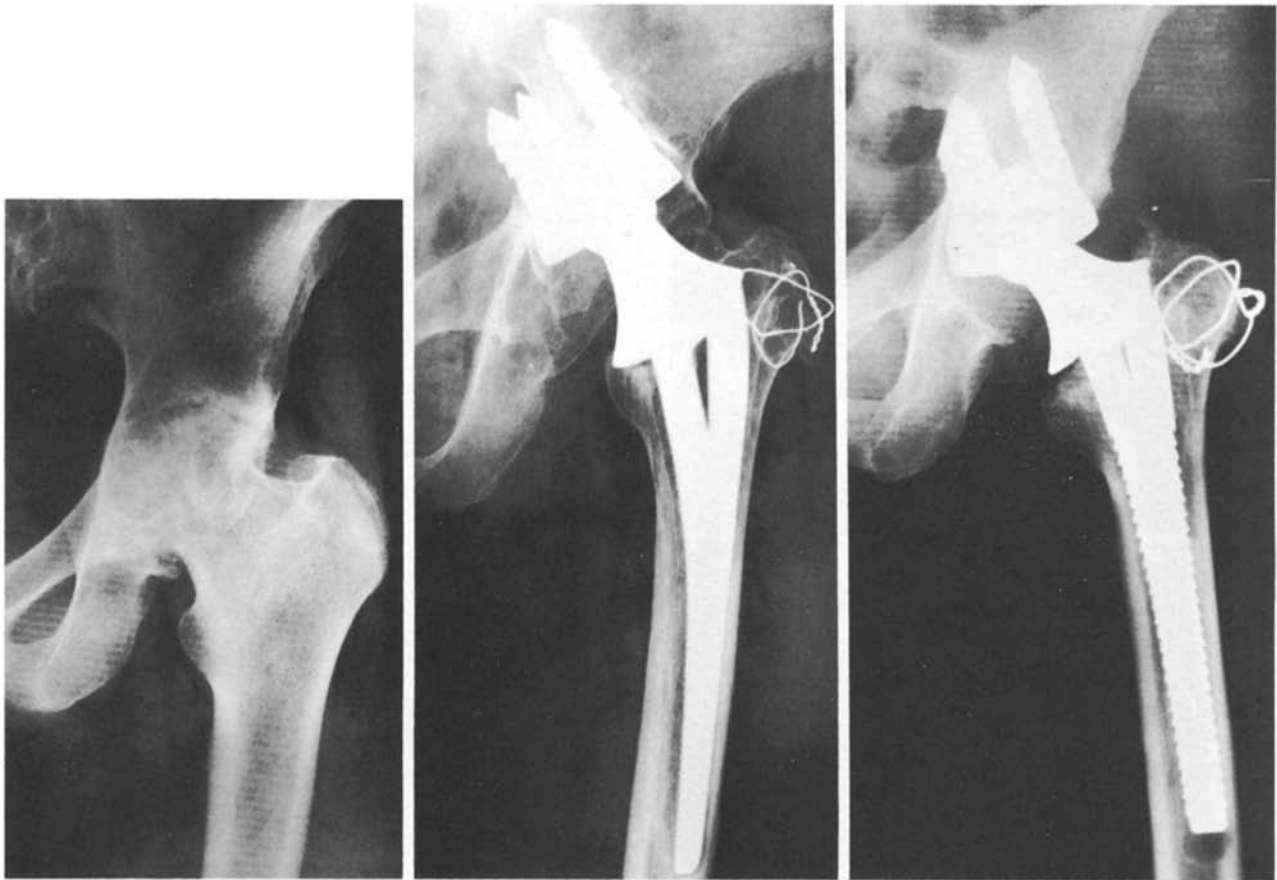


Fig. 11. Loosening was suspected in this case. Female, 42 years old, rheumatoid arthritis. She has moderate pain when walking, and X-ray picture shows radiolucency around the femoral component. Left: before surgery. Middle: 3 years after surgery: our old total hip prosthesis was used. Right: 1 year after second surgery: our new total hip prosthesis was used

not sufficient to fix the stem in place. Accordingly, this kind of loosening differs from that developed in the clear zone which occurs when the bone cement is used. It has been rarely seen since the six different sizes of femoral component stems have been made available.

Non-union of the greater trochanter, as in Fig. 12, was seen in cases where the trochanter did not reattach smoothly due to contracting of muscles surrounding the hip joint, especially the abductors. But none of these non-unions showed any correlation with the clinical results.

Fractures of the femoral shaft were caused by hammering in too large stems in 2 cases and by a postoperative fall down in 1 case. These cannot be considered due to direct complications of the total hip prosthesis.

Reduction of the postoperative dislocation of the total hip prosthesis was easily done. No recurrence was observed.

Discussion

Many experimental and clinical studies have been done on the bone-cement method. At present Charnley et al. advocate that bone-cement is harmless. Their method is currently accepted and most clinicians perform total hip replacement employing this method. However, when we consider the effects of the large quantity of heat generated by polymerization, and the toxicity of monomers, 5% of which reportedly remain even after polymerization, we cannot disregard the adverse effects of bone cement on the human body. Cement is also reported to cause low blood pressure when implanted into the medullary canal. Other drawbacks also have been reported: severe complications are likely to be caused by infection, and the removal of the total bone-cement hip prosthesis becomes extremely difficult; loosening between bone cement and the prosthesis is another problem—this occurs as the postoperative-period lengthens, causing severe pain.

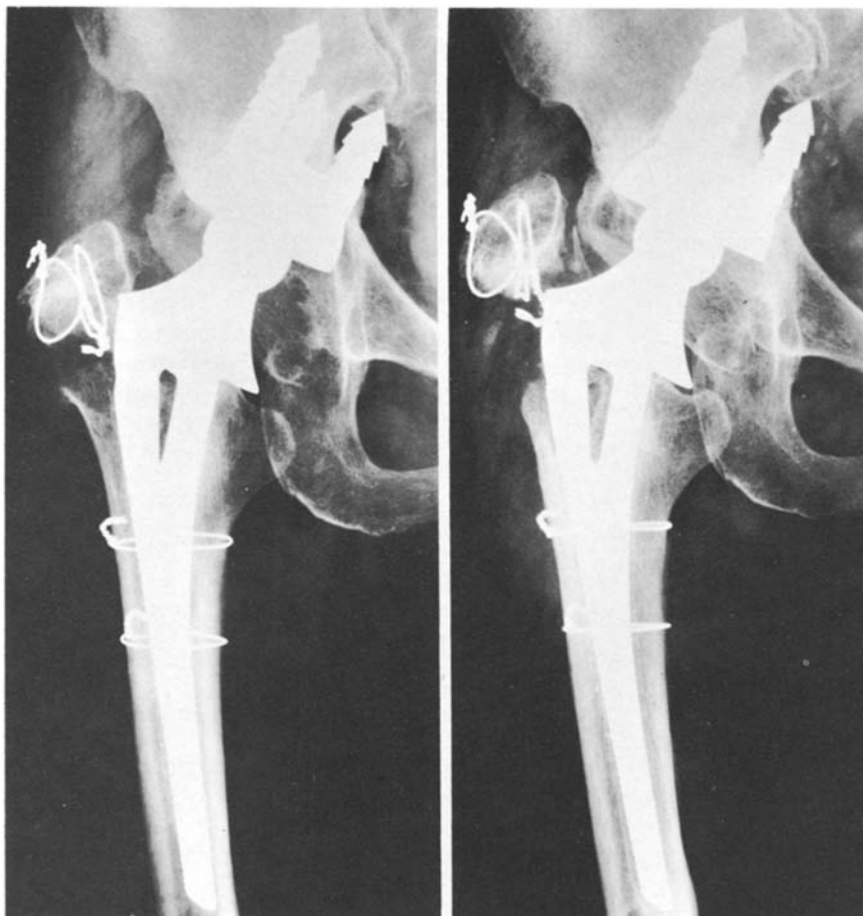


Fig. 12. The case of non-union of the great trochanter. Female, 68 years old, after failure of femoral endoprosthesis. Our old total hip prosthesis was used. Left: 5 months after surgery. Right: 3 years after surgery

In other cases the entire detachment of artificial acetabulum with its bone cement in one solid block has been reported.

The results of our total hip prosthesis were reviewed. We examined the clinical evaluation scores at different postoperative periods, 1, 2, and 3 years, in 154 cases which continued for 3 postoperative years or longer. The score was consistent after the first year when muscles regained sufficient power and bones attained adequate supportability. Some authors reported that patients temporarily maintain good condition when bone cement was used, but that this score dropped after the third year. In contrast, our cases scored high even 5 years after the replacement. This, we believe to be quite remarkable.

Some cases using our old type prosthesis showed a slight shift of the acetabular component or the femoral component. Such phenomena begins about 3 months after the operation when weight-bearing is allowed. The shifts can be grouped into 2 types: in the first, the shift ceases within 1 year or 2, and in the second type, it ceases within 3 or 4 years. In both types the shifting ceased after a certain period and none continued in-

definitely shifting. We did not observe any clinical aggravation due to this shift. The most likely cause was that the acetabular angle and the hammered-in femoral component angle were not appropriate in bearing the patient's weight, and thus the acetabular and the femoral component shifted to their most stable positions. The shift of the acetabular component was mostly due to acetabular hypoplasia. Some occurred when the acetabular component was hammered in too lateral a manner and positioned slightly horizontally. In order to prevent such shifts, the acetabular component should be inserted as medially as possible. When osteophytes exist on the medial side of the acetabulum, a prior resection is necessary.

Shifting of the femoral component was observed in 9 cases operated on using only the old-type prosthesis. In some of these the tip of the stem shifted medially and showed a tendency to valgus. The probable cause was an incomplete removal of the femoral neck which resulted from an improper resection of the femoral head: it was not cut just above the lesser trochanter. Other cases occurred when the medullary canal of the

femur was too large compared with the stem of the femoral component used. The stem could not contact the surrounding cortex within the medullary canal, and it merely floated in soft medullary tissue, failing to be firmly fixed by new bone formation. Two cases in which loosening occurred were of this type, essentially differing from the loosening observed in the Charnley operations. One case showed loosening of the acetabular component. The most likely cause originated at the stem of the femoral component and caused its instability, which in turn led to the loosening of the acetabular component. In order to prevent these loosening we provided 6 different sizes of stem in the new type prosthesis to match the size of the medullary canal, aiming at a maximum self-locking effect.

Through the use of our new type insertion, we can immediately expect a more self-locking effect within the cortex. We do not need to wait for new bone formation around the stem. Accordingly, we will be able to make the postoperative treatment much shorter than before. About this important development we will report in the near future.

Clinical symptoms, such as pain, due to the shifting of the acetabular or femoral components were limited to just 2 cases of loosening. None of the shifts accompanied bone resorption nor any prominent thinning of the bone cortex. If bone-cement had been used here, the acetabular or femoral component could not take its destined course to the proper position; strains thus generated would have been concentrated

on a certain part of the total hip prosthesis. In regard to this, e.g. Chao et al. recently analyzed 58 cases of fracture of the femoral component and reported that the cause was improper fixation by bone cement.

In bilaterally affected patients, unilateral replacement improved the unoperated side in 30% of the cases; the operated side became weight-bearing and relieved weight from the opposite side.

Regarding complications, infection occurred in 1.5% of the cases with our method. Dislocation of the hip prosthesis occurred in 2% of our cases, all immediately after replacement. These were reduced surgically and recurrence has not been observed.

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